AMERICAN SOCIETY OF **CONSULTANT PHARMACISTS**

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December 19, 2002

Lester Crawford, D.V.M, Ph. D.
Deputy Commissioner
Food and Drug Administration
Attn: Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. Crawford:

The American Society of Consultant Pharmacists (ASCP) is pleased to submit comments in response to the October 24, 2002 *Federal Register* notice, "Applications for FDA Approval to Market a New Drug: Patient Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed."[1] ASCP appreciates and supports the Food and Drug Administration's (FDA) proposal for generic drug reform to change guidelines promulgated from the 1984 "Drug Price Competition and Patent Term Restoration Act" (Hatch-Waxman Act)[2]. ASCP acknowledges this proposal represents an important first step towards ensuring that older Americans have more timely access to affordable, quality generic pharmaceuticals.

ASCP is a nonprofit professional association representing approximately 7,000 consultant pharmacists who provide medication management and distribution services to improve the quality of life for seniors who reside in a variety of settings, including community-based home care, assisted living, skilled nursing and other long-term care facilities. In their role as medication therapy experts, ASCP members resolve therapeutic failures and adverse drug reactions for more than seven million patients.

As an integral part of the health care team, consultant pharmacists make recommendations that improve outcomes associated with medication therapy and produce cost-savings for the health care system by reducing the number of adverse drug events. For example, consultant pharmacists in nursing facilities identify and prevent medication problems through evaluation of patients' drug regimens. These interventions increase the frequency of optimal therapeutic outcomes by 43%

[1] Federal Register, Vol. 67, No. 206 – Thursday, October, 24, 2002/Proposed Rules
[2] HR. 3605 and S. 2926, 98th Cong., 2nd Sess. (1984).

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and save $3.6 billion annually in costs from avoided medication-related problems.[3] Often consultant pharmacists recommend alternative medications, such as generic products that can save the health care system and the patient money. To allow seniors increased access to more affordable generics, ASCP supports the FDA in its attempt to build consensus towards getting affordable pharmaceuticals to market in a timely manner. The proposed rule contains multiple objectives that will ultimately increase access to generic medications, including:

- One thirty month stay per abbreviated new drug application, and
- Provides clarity regarding requirements for new drug application that alleviate confusion and often delays generic entries.

As directed in the Federal Register notice of October 24, 2002, the comments submitted by ASCP will focus on FDA's proposed recommendations. ASCP will present support for the proposed rule as a first step to improving access to generics by 1) addressing the positive impact generic reforms will have for seniors and their use of medications, 2) briefly addressing the need for further restructuring of federal reimbursement policies to increase access to generic medications, and 3) explaining the rationale in support of the FDA proposed rule.

1. Changes to "Hatch-Waxman" - Positive Impact for Seniors and Use of Medication

According to the Centers for Medicare and Medicaid Services (CMS), older Americans, those 65 years of age or older, make up 13 percent of the population but purchase approximately 35 percent of all outpatient prescriptions. This spending accounts for just over 40 cents of every dollar spent on prescription drugs.[4] At these levels, if Congress and the White House pass a drug benefit under Medicare, which currently covers approximately 98 percent of older Americans, drug expenditures of older Americans will spiral out of control.[5]

Prescription drug spending is now the fastest-growing part of health care costs.[6] Between 1999 and 2000 alone, spending on medications increased by approximately 17%--the sixth year of double-digit increases.[7] As prescription drug expenditures continue to grow for the entire adult population, this ever-increasing figure is a particular problem for the elderly because:

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[3] J.L. Bootman, L.D. Harrison, and E. Cox. "The health care cost of drug-related morbidity and mortality in nursing facilities." Arch Int Med (1997).
[4] Centers for Medicare and Medicaid Services (CMS). See [www.cms.gov]
[5] Stuart H. Altman, Ph.D. "Controlling Spending for Prescription Drugs" (2002).
[6] Ibid., 9.
[7] Robert Steinbrook, M.D. "The Prescription Drug Problem" (2002).

- they utilize three more times prescriptions than their younger counterparts,

- older Americans typically live on fixed incomes, and

- they often lack true prescription coverage.[8]

ASCP understands the need for innovation among the pharmaceutical industry to encourage the development of medications that are more effective and cause fewer reduce side effects. This is especially true for the chronically ill, seniors who primarily reside in nursing facilities or other long-term care settings served by ASCP members. These seniors often suffer from one or multiple chronic disease states, such as adult onset diabetes, depression, and psychosis related to dementia. For some of these conditions, such as depression, and psychosis, a variety of new and old medications are available for treatment. While the older medications are available in less-expensive generic formulations, newer medications often produce better outcomes for seniors. For example, side effects from older medications for depression or psychosis may cause seniors to fall, resulting in hip fractures that could lead to death or permanent debilitation in seniors. Newer medications for these conditions do not have the severe side effects of some older medications but are much more expensive.

No matter how well a medication works, economics is integral to the selection of medication. While consultant pharmacists work with caregivers, prescribers, and others responsible for the care of seniors to optimize medication therapy, increasing fiscal restraints caused by skyrocketing drug costs constrains the ability of ASCP members to optimize medication therapy. Part of the reason is the increased need to use newer medications. As the patents expire on these medications, seniors should be able to access these products in generic form. However, this cannot happen if brand name manufacturers have nearly unbridled ability to delay the introduction of generic forms onto the market. Therefore, ASCP supports proposals to put generics on the market more quickly. The provisions in the FDA proposal are a positive first step to achieving this goal.

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[8] CP Thomas, G Ritter, and SS Wallack. "Growth in Prescription Drug Spending Among Insured Elders" (2001).

2. Need for Restructuring: Government Reimbursement Policies Limit Ability to Dispense Generics

Even if this proposed rule is adopted, reimbursement policies for Medicaid restrict access to generic medications. Although not germane to the FDA proposed rule, ASCP will use this opportunity to publicly comment on the reimbursement policies implemented by the federal government, namely CMS, which inhibit the ability of pharmacists to dispense generics when appropriate. One such reimbursement policy that needs to be restructured is the federal upper limits (FUL) list.

Under federal regulations at 42 CFR 447.332, in accordance with section 1902(a)(30)(A) of the Social Security Act, CMS has the authority to set upper payment limits for services under the Medicaid program. As it relates to multi-source generic medications, the FUL is based on an amount that is equivalent to 150% of the published price for the least costly therapeutic equivalent. To establish this list of price limits, the following guidelines must be followed:

- Three or more versions of generic medication supply is listed in the national compendia (i.e., First Databank)
- Three or more versions of the product exist
- All multi-source products are classified as an A-rated product by the FDA[9]

Unfortunately, ASCP and other pharmacy organizations have found in numerous instances where multi-source generics on the FUL list do not meet one or more of these guidelines. These discrepancies represent "bad government policy" for pharmacists and consumers, because it then becomes cost prohibitive to dispense the more affordable generic medication.

For example, because of an insufficient national supply of valproic acid capsules (250mg), the average purchasing price for this anticonvulsant medication has increased nearly 200% to $37.64. Although the need for a multi-source generic to be of "national supply" is required to be on the FUL list, valproic acid still remains on the list at a reimbursement level of only $18.82. If a pharmacist attempts to dispense this more affordable anticonvulsant generic medication, he or she would lose approximately $18 per script. These discrepancies are exacerbated even further when the state Medicaid programs implement the FUL errors under state maximum-allowable cost (MAC). CMS and other federal government officials should insist that FUL guidelines for multi-source generics are fully enforced. Otherwise, incentives for pharmacists to dispense generic alternatives almost become nil.

[9] 42 CFR 447.332 (also see 52 FR 28648 dated July 31, 1987 and 51 FR 29560 dated August 19, 1986).

Again, ASCP recognizes this last section is not germane to the FDA proposed rule, but the notions expressed by ASCP need to be reviewed by federal policymakers if the final objectives of the FDA proposed rule are ever going to be fully realized by older Americans who purchase medications on a daily basis.

3. Policy Background and FDA's Recommended Changes for "Hatch-Waxman"

Although the "Hatch-Waxman" act was carefully crafted in Congress to ensure fair competition, loopholes within the law have been found and subsequently exploited. For example, current interpretation of the law allows brand manufacturers to extend the life of their drug patents by issuing successive "late-listed patents" that unfairly delays introduction of generic medications. Delayed introduction produces denied access by consumers to significant cost savings when utilizing generic drugs. Many policymakers and health care experts agree that "greater use of generic medications, which in general cost substantially less than brand drugs, affords an effective means for controlling cost growth while maintaining quality of health care."[10] The recommended changes to "Hatch-Waxman" listed in FDA's proposed rule will not only achieve cost savings, but will ultimately improve the health care of older Americans by increasing the affordability of necessary drug therapies.

Required Patent Information for NDAs

One objective of the proposed rule is to tighten the requirements and increase disclosures for drug patent listings. Currently, brand manufacturers are able to file a permitted listing for active ingredients, drug formulations, and method of use.[11] Yet, many brand manufacturers take advantage of the FDA Orange Book listing process established under "Hatch-Waxman" by listing patents for other unrelated characteristics such as drug packaging and drug metabolites. This occurs because the FDA currently relies upon applicant assurances that listed information is in accordance with regulatory requirements. This manipulation of the FDA listing process only further confuses acknowledgement of the correct patent "end date(s)" and delays access to generic drug alternatives.

Under the proposed rule, the FDA defines which patent information is required and allowed for patent listing. The proposed rule limits patent listing information to that of drug substance, drug product, method of use, and product by process patents only. ASCP supports the FDA in denoting exactly what types of information is allowed and proper for drug listings. ASCP also supports this

[10] National Institute for Health Care Management Foundation (NIHCM), "Factors Affecting the Growth of Prescription Drug Expenditures" (1999).
[11] Ibid., 3.

objective because it will significantly reduce the number of opportunities to list inappropriate patents as a means to prevent access to generic drug alternatives. Similar support and clarity of rationale is also shared by the Federal Trade Commission (FTC).[12]

One 30-Month Stay

Another objective of the proposed rule is to limit the number of 30-month stays to only one per ANDA. A similar recommendation is shared by the findings of the FTC in their recent report, *Generic Drug Entry Prior to Patent Expiration.*[13] In this report, the FTC found certain brand manufacturer practices to be questionable when seeking to obtain multiple 30-month stays of FDA approval for generic drugs. To counter these questionable practices, the FTC recommends that the generic drug approval process be altered to favor generic manufacturers by limiting the number of stays.

ASCP concurs with this recommendation relating to 30-month stays, but the changes in the FDA proposed rule does not entirely complete its objective. While the proposed rule seeks to limit the ability of brand manufacturers to obtain multiple 30-month stays, it is silent as it applies to limiting stays relating to "late-listed patents." ASCP proposes that FDA consider changes submitted under Senate passed legislative language in S. 812, the "Greater Access to Affordable Pharmaceuticals Act" (GAAP) of 2002. Sponsors of GAAP, Senators John McCain (R-AZ) and Charles Schumer (D-NY), sought to limit the 30-month stay on generic approval to a one time only stay.

Under GAAP, brand manufacturers would be prohibited from claiming patent infringement, thereby being awarded an automatic 30-month stay, unless a patent was listed within 30 days of NDA approval. This qualification provides a disincentive for brand manufacturers to late-list patents in an attempt to extend patent life. Again, the FDA proposed rule is silent in this respect and contains no provision of when a patent must be listed in order to qualify for a 30-month stay. Consequently, brand manufacturers will still be able to delay generic approval by continuously late-listing patents. ASCP recommends that FDA incorporate this aspect of S. 812 to fulfill this objective of the proposed rule.

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[12] Statement by Federal Trade Commission Chairman Timothy Muris on "FDA's Proposals to Improve Consumer Access to Lower-Cost Generic Drugs" (October 2002). See [www.ftc.gov]
[13] Federal Trade Commission. "Generic Drug Entry Prior to Patent Expiration" (October 2002).

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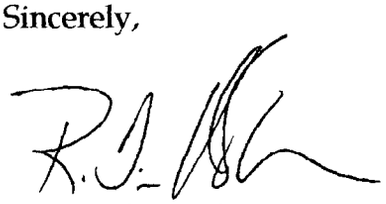
Conclusion

ASCP thanks the FDA and Deputy Commissioner Crawford for proposing these modifications to the generic drug approval process and for the opportunity to provide additional comments. ASCP remains supportive of the FDA proposed rule and requests that FDA consider further modifications to ensure access to affordable pharmaceuticals in a timely manner.

If ASCP can be of any further assistance regarding the issues addressed by these comments, please contact Tim Webster, ASCP Executive Director by phone at 703-739-1316, ext. 200 or email at twebster@ascp.com.

Sincerely,



R. Timothy Webster

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